Kentucky Board of Pharmacy

# Compounded Semaglutide and Tirzepatide Compliance Alert

**November 14, 2025**

The Kentucky Board of Pharmacy (Board) has received inquiries regarding resident and non-resident pharmacies obtaining and dispensing compounded GLP-1 and GIP medications—such as semaglutide and tirzepatide—from 503B outsourcing facilities. Semaglutide is commercially available as Ozempic™ and Rybelsus™ for diabetes and as Wegovy™ for weight loss. Tirzepatide is commercially available as Mounjaro™ for diabetes and Zepbound™ for weight loss.

As stated in the Board's Opinion and Declaratory Order dated May 22, 2024, pharmacies are expected to procure compounded products only from outsourcing facilities that are legally authorized to compound the product and only dispense such products if the pharmacist is legally authorized to do so in Kentucky.

https://pharmacy.ky.gov/Documents/Declaratory%20Opinion_Aquring%20503B%20Compounds%20for%20Dispensing.pdf

## Bulk Drug Substances for 503B Compounding

When compounding, outsourcing facilities may use bulk drug substances only if the substances:

- Are used to compound drug products that appear on FDA's drug shortage list at the time of compounding, distribution, and dispensing; **or**
- Appear on the 503B Bulks List or Category 1 of the *Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

503B Bulks List

category 1 of the Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA Shortage List

## FDA Background on Semaglutide and Tirzepatide

**Tirzepatide:**
On March 5, 2025, the district court denied the plaintiffs' preliminary injunction motion in *Outsourcing Facilities Association v. FDA*, 4:24-cv-00953 (N.D. Tex.). Consistent with FDA's February 11, 2025 update:

- For state-licensed pharmacies or physicians compounding under Section 503A, the period of enforcement discretion has ended.

- For outsourcing facilities under Section 503B, FDA does not intend to take action for violations arising from conditions dependent on tirzepatide injection products' inclusion on the drug shortage list until **March 19, 2025**.

**Semaglutide:**
On April 24, 2025, the district court denied the plaintiffs' preliminary injunction motion in *Outsourcing Facilities Association v. FDA*, 4:25-cv-00174 (N.D. Tex.). Consistent with FDA's March 10, 2025 update:

- For state-licensed pharmacies or physicians compounding, dispensing, or distributing semaglutide injection products under Section 503A, the period of enforcement discretion has ended.
- For outsourcing facilities under Section 503B, FDA does not intend to take action for violations arising from conditions dependent on semaglutide injection products' inclusion on the drug shortage list until **May 22, 2025**.

https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize

**When Is 503B Compounding of Semaglutide or Tirzepatide Permissible?**

Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA), outsourcing facilities may compound medications without patient-specific prescriptions if they comply with current good manufacturing practice (cGMP) and other requirements. Critically, 503B facilities may not compound products that are "essentially copies" of FDA-approved drugs unless the approved drug is on the FDA shortage list.

**Is Adding Another Commercially Available Drug, Such as B12 or B6, Considered Compounding an Essentially Copy of a Commercially Available Product?**

The FDA has explained:

*A compounded drug product is considered essentially a copy of a commercially available drug product if it contains the same active pharmaceutical ingredient(s) (APIs) in the same, similar, or easily substitutable strength, and is intended for the same route of administration—even if combined with other ingredients—unless a prescriber determines and documents that there is a clinical difference for an individual patient.*

**Important Clarification Regarding 503B Outsourcing Facilities**

503B outsourcing facilities do not distribute compounds pursuant to patient-specific prescriptions. Because they operate without prescriptions, outsourcing facilities cannot rely on the exception that allows compounding an essential copy when a prescriber documents a clinical difference for an individual patient. That exception applies only to traditional compounding under Section 503A, where the pharmacy or physician is compounding directly for an identified patient.

Therefore:

Any compounding that relies on a prescriber's determination of a clinical difference must occur within a 503A pharmacy, not a 503B outsourcing facility.

A 503B outsourcing facility may not compound an essentially copy of an FDA-approved drug unless that product appears on the FDA drug shortage list or is otherwise permitted under Section 503B (e.g., API is on the 503B Bulks List or Category 1 List).

**Bottom Line**

Compounding of commercially available products is allowable only in narrow circumstances. Because outsourcing facilities do not distribute compounds pursuant to patient-specific prescriptions, they cannot use the clinical-difference exception to justify compounding semaglutide or tirzepatide. Neither drug appears on the 503B Bulks List or Category 1 list, and both have been removed from the FDA drug shortage list. Accordingly, 503B outsourcing facilities generally may not lawfully compound these drugs.

The Board is responsible for protecting public health. Compounding or dispensing compounded semaglutide or tirzepatide in a manner that does not conform to federal and state requirements may result in enforcement action by the FDA and the Kentucky Board of Pharmacy.

Any pharmacy permitted by the Kentucky Board of Pharmacy that dispenses unapproved drug products to patients in the Commonwealth, unless authorized by law, may be subject to disciplinary action.